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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)  
9896.141.3.1

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on

Oct. 16, 2006

Signature

Stacy Bickel

Typed or printed  
name

Stacy Bickel

Application Number

10/759,853

Filed

Jan. 15, 2004

First Named Inventor

Patrick Guire, et al.

Art Unit

1711

Examiner

Terressa M. Boykin

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)☒

attorney or agent of record.

Registration number 54,647

☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34

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Oct. 16, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below\*.☒

\*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: GUIRE, et al.

Attorney Docket No. 9896.141.3.1

Application No.: 10/759,853

Examiner: Terressa M. Boykin

Filed: January 15, 2004

Group Art Unit: 1711

For: SELF ASSEMBLING MONOLAYER COMPOSITIONS

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**Arguments Presented For Pre-Appeal Brief Review**

The Examiner issued a Final Office Action on May 26, 2006 finally rejecting claims 29 and 46. Applicants responded on July 21, 2006 with a first reply within 2 months of the date of the Final Action. In response, the Examiner issued a second Final Office Action dated August 2, 2006, in which she rejected claims 29 and 46 for a third time. The Examiner did not issue an Advisory Action. Applicants are appealing the Final Action of May 26, 2006. These arguments are being filed concurrently with a Notice of Appeal.

Arguments

The Application includes 23 pending claims, numbered 29-51. Claims 29 and 46, the only independent claims, have been rejected three times.

The Examiner rejected claims 29 and 46 under 35 U.S.C. § 102(b) or (e) as being anticipated by Noble et al., “Biomaterials Tutorial: Drug Delivery Systems”. The tutorial is an internet posting published on the University of Washington website. This rejection is improper because the cited tutorial is not proper 102 (b) or (e) art.

The internet posting is not proper 102(b) art. Section 2128 of the MPEP relates to internet postings and states that “[i]f the publication does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. § 102 (a) or (b)”. The Examiner did not provide proof regarding the date that the tutorial was publicly posted. In fact, this publication does not include such a post date. Rather, the only date indicated is the 12/07/05 date, which appears to be the date the Examiner printed the material. This date is significantly later than the priority date of the application, which is July 17, 2001. Therefore, the 102(b) rejection is improper and should be withdrawn and the claims promptly allowed.

The internet posting is not proper 102(e) art. The pertinent section of the Code, 35 U.S.C. § 102(e), states, in part, that a patent will be issued unless the invention was disclosed in “(1) an application for patent, published under section 122(b)... or (2) a patent granted on an application for patent... [or] international application [that designates] the United States and ... [is] published under article 21(2)... in the English language.” The Tutorial, posted on the internet, and cited by the Examiner, is neither an

application for patent nor a patent granted on an application for patent. Therefore, the 102(e) rejection is improper and should be withdrawn and the claims promptly allowed.

Furthermore, even if the above deficiencies with the reference were not present, the rejection would still be improper because the reference does not disclose each and every element of the claims. “A claim is anticipated *only* if *each and every* element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) emphasis added.

The reference does not disclose or suggest medical devices coated with a self-assembling monolayer that is covalently attached to a surface of the medical device through latent reactive groups. Accordingly, the reference fails. Therefore, the rejection is improper and should be withdrawn and the claims promptly allowed.

The Examiner rejected claims 29 and 46 under 35 U.S.C. § 102 (b) or (e) as being anticipated by “Microfabricated Microneedles for Gene and Drug Delivery”, McAllister et al. and “A controlled-release microchip”, Santini et al. These rejections are improper because the references are not proper 102(b) or 102(e) art.

The 102(b) rejections based on McAllister et al. and Santini et al. are improper because they fail to disclose each element of the rejected claims. As outlined above, a reference does not anticipate a claim if it does not disclose each and every element of the claim. (See *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

The McAllister et al. and Santini et al. abstracts do not disclose or suggest all of the elements of the rejected claims. The cited abstracts do not disclose medical devices coated with a self-assembling monolayer that is covalently attached to a surface of the medical device through latent reactive groups. Accordingly, the references fail. Therefore, the cited abstracts do not anticipate claims 29 and 46. The rejection should be withdrawn and the claims promptly allowed.

The references are not proper 102(e) art because they are not a U.S. patent, a U.S. patent application publication or a WIPO publication of an international application under PCT article 21(2) as required by 35 U.S.C. §102(e). Therefore, the rejections are improper and should be withdrawn and the claims promptly allowed.

The Examiner rejected claims 29 and 46 under 35 U.S.C. § 102(e) as being anticipated by LaVan, DA, McGuire T, Langer R. “Small-scale systems for in vivo drug delivery”. The rejection is improper for two reasons. First, this reference is not prior art because it was published on September 30, 2003, which is after the priority date, July 17, 2001, of the present application. Second, this abstract is not proper 102(e) prior art since it is not a U.S. patent, a U.S. patent application publication or a WIPO publication of an international application under PCT article 21(2) as required by 35 U.S.C. §102(e).

Furthermore, even if the above deficiencies with the reference were not present, the rejection would still be improper. As outlined above, a reference anticipates a claim only if it discloses each and every element of the claim. (See *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). The reference does not disclose medical devices coated with a self-assembling monolayer that is covalently

attached to a surface of the medical device through latent reactive groups. Therefore, the rejection is improper and should be withdrawn and the claims promptly allowed.

The Examiner rejected claims 29 and 46 under 35 U.S.C. § 102(e) as being anticipated by Zhong, U.S. Pat. No. 6,468,649. The rejection is improper because the reference does not disclose each and every element of the claims. As outlined above, a reference anticipates a reference only if it discloses each and every element of the claim. (See *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Zhong does not disclose or suggest medical devices coated with a self-assembling monolayer that is covalently attached to a surface of the medical device through latent reactive groups. Therefore, Zhong does not anticipate claims 29 and 46 and the rejection should be withdrawn and the claims promptly allowed.

In light of the above, the Applicants respectfully submit that each of claims 29-51 is in condition for allowance. Because these are the only claims pending in the application, prompt issuance of a Notice of Allowance in this case is courteously solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'M.J.S. Graham', with a long horizontal flourish extending to the right.

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